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REMARKS

In the Office Action, claims 1, 3-7, 9-13, and 15-28 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,456,708 to Doan et al. in view of U.S. Patent No. 5,575,814 to Giele et al.

Following is a discussion of the patentability of each of the pending claims.

Independent Claim 1

Claim 1 recites an implantable lead comprising a helical fixation element extendable and retractable from a distal end of the lead. The distal end of the lead comprises (a) an inner header tube comprising an electrically conductive material that is substantially transparent fluoroscopically to allow an unobstructive fluoroscopic view of the helical fixation element, the helical fixation element is housed within the inner header tube when in a retracted position, and the inner header tube has a distal end, (b) an outer header tube comprising an electrically insulating material, the outer header tube is coaxial to the inner header tube, and (c) a distal tip collar attached to the distal end of the inner header tube, and the distal tip collar comprises a material that is substantially opaque fluoroscopically, and the distal tip collar is electrically coupled to the distal end of the inner header tube.

The Doan et al. reference is directed to providing a lead (10) with a substantially transparent fluoroscopic header tube that permits direct and rapid positional verification of a helical electrode. The lead (10) has a helix electrode (30) for piercing tissue to be stimulated (see Figure 1). A collar (30) is provided at the distal tip of the lead to facilitate fluoroscopic verification of the extension of the helix electrode relative to the lead tip during lead fixation. The collar is mounted within a recess (41) of an insulative header tube (24) adjacent the lead tip surface (26). The collar is electrically isolated and is secured to the header tube by means of a bonding agent such as a urethane adhesive.

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The Doan et al. reference does not disclose or suggest an inner header tube housing a helical fixation element and comprising an electrically conductive material that is substantially transparent fluoroscopically to allow an unobstructive view of the helical fixation element. The Doan et al. reference discloses an electrically insulative header tube (24) that houses the helical electrode (30).

The Giele et al. reference discloses a lead having a distal portion with a sleeve (36) and an electrically conductive tube coaxial and within the sleeve. The sleeve is provided with a helix engaging collar (46) that engages a helix in a screw like fashion such that the helix is relatively advanced or retracted when the helix is rotated with respect to the sleeve. It is noted that the helix is advanced into body tissue by retracting the sleeve relative to the helix such that the helix remains fixed relative to the lead body during retraction and advancement of the helix. A distal tip electrode (28) is connected to the proximal end of the lead by an electrically conductive tube (37), core element (44), and an inner conductor coil (34).

The Giele et al. reference does not disclose or suggest an inner header tube housing a helical fixation element and comprising an electrically conductive material that is substantially transparent fluoroscopically to allow an unobstructive view of the helical fixation element. The Giele et al. reference discloses an electrically conductive tube (37) that is located within the helix (50). Furthermore, the Giele et al. reference does not disclose or suggest a distal tip collar attached to a distal end of the inner header tube, wherein the distal tip collar comprises a material that is substantially opaque fluoroscopically and electrically conductive. In the Giele et al. reference, the collar (46) is integral with the sleeve (36), and the sleeve is preferably made of molded polyurethane. As such, the sleeve and collar are electrically nonconductive and transparent fluoroscopically. The sleeve and collar are electrically nonconductive because the tip electrode is electrically coupled to the electrically conductive tube, core element, and inner conductor, and it appears that the sleeve electrically isolates these components from the other components of the lead. Thus, the collar (46) does not comprise a material that is substantially opaque fluoroscopically and electrically conductive.

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Furthermore, it would not be obvious to combine the teachings of the Doan et al. and Giele et al. reference because the helical electrode (24) of the Doan et al. reference will not function as intended. The Doan et al. reference is directed to providing a lead with a helical electrode to serve the dual purpose of providing active fixation to heart tissue and providing electrical continuity with an implantable cardiac device. This electrical continuity is provided by electrically coupling the helical electrode with a connector pin (20) at the proximal end of the lead with a helix shaft (34) and flexible conductor coil (40). In the Giele et al. reference, the helix (50) serves the single purpose of providing active fixation to heart tissue, and the helix is not electrically coupled to a cardiac stimulation device. As can be seen in Figure 2, the tip electrode (28) is electrically coupled to a cardiac stimulation device via the electrically conductive tube, core element, inner conductor (34), etc.

Accordingly, it is respectfully submitted that claim 1 is in condition for allowance.

Dependent Claims 3-6, 20, and 22-24

Claims 3-6, 20, and 22-24 depend from claim 1 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 7

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 7 is in condition for allowance.

Dependent Claims 9-12, 21, 25, and 26

Claims 9-12, 21, 25, and 26 depend from claim 7 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 13

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 13 is in condition for allowance.

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Dependent Claims 15-19, 27, and 28

Claims 15-19, 27, and 28 depend from claim 13 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

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CONCLUSION

In light of the above remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

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Date

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